

MiraVista *Histoplasma* Urine Antigen Lateral Flow Assay (LFA)

Background

Histoplasmosis is a systemic infection caused by the dimorphic fungus *Histoplasma capsulatum*. Rapid diagnosis is important for early initiation of treatment in progressive disseminated and acute pulmonary histoplasmosis cases. Antigen detection has been proven useful for rapid diagnosis.

Development

We have developed an easy to use immunochromatographic lateral flow assay (LFA) for the visual detection of *Histoplasma* galactomannan antigen in urine.








The MiraVista *Histoplasma* Urine Antigen LFA test can aid in diagnosis of *Histoplasma* infection.

Performance

The MiraVista *Histoplasma* Urine Antigen LFA has a proven clinical sensitivity of 93.18% and 96.96% specificity relative to culture proven cases with a limit of detection (LoD) of 1.8 ng/mL in clinical specimens.


<i>Histoplasma</i> Urine Antigen LFA	Culture	
	Positive (Case)	Negative (Control)
Positive	41	9
Negative	3	287
TOTAL	44	296

Advantages of the MiraVista Urine *Histoplasma* Antigen LFA

-  **Rapid 3 step process**
-  **Results are ready in approximately 40 minutes**
-  **Quick turnaround time allows for timely diagnosis and treatment**
-  **Non-invasive specimen collection**
-  **No complex equipment required**
-  **CE Marked product**
-  **Can be performed in low complexity clinical settings**


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*** Prep**



Pipette 25 μ l sample diluent into supplied tube.

1 Dilute



100 μ l Urine Sample
25 μ l Sample Diluent

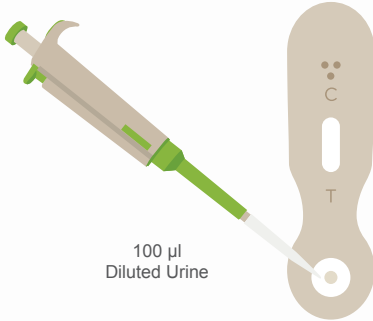
Mix urine sample thoroughly. Pipette 100 μ l urine sample into tube with sample diluent.

2 Mix



Securely close the tube and mix.

3 Pipette

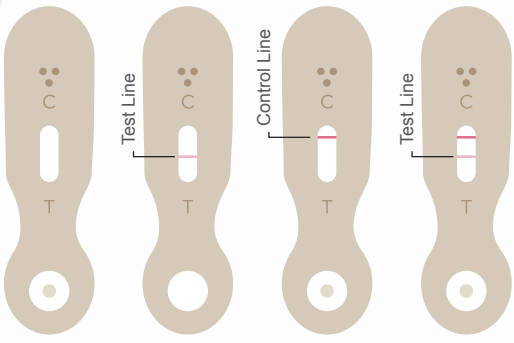


100 μ l Diluted Urine

Lay device on a flat level surface.
Pipette 100 μ l diluted urine onto the sample pad.
Read results after 40 minutes.

40 MIN

*** Read**



INVALID **INVALID** **NEGATIVE** **POSITIVE**

Absence of a control line indicates an **INVALID** result.
Presence of both a test and a control line indicates a **POSITIVE** result. Absence of a test line and presence of a control line indicates a **NEGATIVE** result.

FOR REFERENCE ONLY. Refer to Package Insert for Complete Instructions For Use.

MiraVista *Histoplasma* Urine Antigen Lateral Flow Assay is a CE Marked product.
Not FDA cleared. Not available in the U.S.

